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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,564	05/14/2001	Raymond G. Goodwin	2519-A	2135

22932 7590 01/06/2004

IMMUNEX CORPORATION  
LAW DEPARTMENT  
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SEATTLE, WA 98101

EXAMINER

ROMEO, DAVID S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 01/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/855,564

Applicant(s)

GOODWIN ET AL.

Examiner

David S Romeo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-18 is/are pending in the application.
- 4a) Of the above claim(s) 15-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1003.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**

Claims 15-18 are pending.

Applicant's election of group II, claim 18, in Paper No. 18 is acknowledged.

- 5    Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

- Claims 15-17 are withdrawn from further consideration pursuant to 37 CFR  
10    1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the paper filed 10/20/2003.

***Claim Rejections - 35 USC § 102***

- The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that  
15    form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- 20    (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

- 25    Claim 18 is rejected under 35 U.S.C. 102(e) as being anticipated by Bram (A).

Bram teaches (14) functionally active polypeptide components of TACI. A functionally active fragment includes the extracellular domain, which binds ligand. The extracellular domain corresponds to the N-terminal fragment of TACI, e.g., from the first amino acid

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residue of mature TACI to the transmembrane domain. In a specific embodiment, the extracellular domain has the amino acid sequence corresponding to about residue 1 to about residue 166 of SEQ ID NO:6. The ligand-binding region of TACI is a sub-fragment of the N-terminal fragment corresponding to the extracellular domain. See paragraph bridging columns 12-13. The amino acid sequence of Bram's SEQ ID NO: 6 comprises the amino acid sequence of the present application's SEQ ID NO: 2, as indicated below (Qy = the present application's SEQ ID NO: 2) (Db = Bram's SEQ ID NO: 6):

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10 ; Sequence 6, Application US/08810572
; Patent No. 5969102
; INFORMATION FOR SEQ ID NO: 6:
; SEQUENCE CHARACTERISTICS:
;   LENGTH: 166 amino acids
;   TYPE: amino acid
15 ;   STRANDEDNESS: single
;   TOPOLOGY: linear
;   MOLECULE TYPE: peptide
;   HYPOTHETICAL: NO
;   FRAGMENT TYPE: N-terminal
20 ;   ORIGINAL SOURCE:
;   ORGANISM: Homo sapiens

Query Match          100.0%; Score 904; DB 2; Length 166;
Best Local Similarity 100.0%; Pred. No. 4.8e-90;
25 Matches 165; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy      1 SGLGRSRRGGRSRVDQEERFPQGLWTGVAMRSCPEEQYWDPLLGTCSCKTICNHQSQRT 60
        ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      2 SGLGRSRRGGRSRVDQEERFPQGLWTGVAMRSCPEEQYWDPLLGTCSCKTICNHQSQRT 61

Qy      61 CAAFCRSLSCRKEQGKFYDHLRLDCISCSICGQHPKQCAYFCENKLRSFVNLPPELRRQ 120
        ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      62 CAAFCRSLSCRKEQGKFYDHLRLDCISCSICGQHPKQCAYFCENKLRSFVNLPPELRRQ 121

35 Qy      121 RSGEVENNSDMSGRYQGLEHRGSEASPALPGLKLSADQVALVYST 165
        ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      122 RSGEVENNSDMSGRYQGLEHRGSEASPALPGLKLSADQVALVYST 166.

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Bram also teaches chimeric TACI proteins generated by joining a functional domain of a TACI protein, such as the ligand binding domain, with the complementary domain of another protein, e.g., an alternative receptor. Chimeric constructs can also be

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prepared with a functionally active fragment of a TACI protein and another functionally active molecule. For example, the extracellular domain of a TACI protein may be joined to the Fc domain of an immunoglobulin. See column 17, full paragraph 1. Accordingly, Bram teaches a TACI:Fc protein comprising an amino acid sequence selected from the group consisting of (a) amino acids 2-166 of SEQ ID NO: 2; (b) amino acids at least 75% identical to amino acids 2-166 of SEQ ID NO: 2; and (c) fragments of amino acids 2-166. Furthermore, a chemical composition and its properties are inseparable. Therefore, the properties applicant discloses and/or claims, i.e., "retain the biological ability to bind TACI-L," are necessarily present in Bram's protein.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 18 is indefinite because it recites the term "TACI-L." Because the instant specification does not identify that material element or combination of elements which is unique to, and, therefore, definitive of "TACI-L" an artisan cannot determine what additional or material limitations are placed upon a claim by the presence of this element. The metes and bounds are not clearly set forth.

### ***Conclusion***

Claim 18 is not allowable.

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ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306

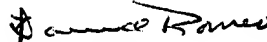
AFTER FINAL (703) 872-9307

IN ADDITION TO THE OFFICIAL RIGHTFAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

  
DAVID ROMEO  
PRIMARY EXAMINER  
ART UNIT 1647

DSR  
DECEMBER 30, 2003